K971685

ST Review Station

510(k) Summary

AUG 12 1997

Submitter:	Mortara Instrument, Inc.
Address:	7865 North 86th Street Milwaukee, WI 53224
Telephone/Fax:	(414) 354-1600/354-4760
Contact:	Regulatory Affairs Manager or Director
Prepared:	August 8, 1997
Proprietary Name:	ST Review Station
Common/Classification Name:	ST Segment Display
Predicate Device:	ELI 100/STM and ST Central Station

New Device Description:

The ST Review Station is an adjunct to the ELI 100/STM Electrocardiograph (12-Lead Diagnostic Electrocardiograph) to provide rapidly responsive trend data originating from the ELI 100/STM Electrocardiograph and associated patient population. The ST Review Station utilizes a PC based operating system with specially developed software that provides for the means to graphically view and/or present the ECG data captured and stored by the ELI 100/STM (legally marketed predicate device – K895232), including ST segment measurements.

Intended Use:

The ST Review Station is intended to allow Physicians and/or Clinical personnel from ER, Cath Lab, ICU, and other related settings to retrospectively review/analyze stored ECG data. By being able review/analyze ECG trends, including ST segment measurements, Clinicians and/or Physicians have access to information to assist in their ability to detect changes in a patients physiological condition and therefore enabling them to respond accordingly to a patients medical needs.

Comparison to Predicate Devices:

See Attached Table (Attachment 1)

Non-Clinical Performance Data:

To ensure that the ST Review Station did not alter the integrity of the ECG data and ST segment measurements received and stored from the ELI 100/STM, the ST Review Station was subjected to verification and validation practices appropriate to determine that it is safety and effective for its intended use.

Performance Data Conclusion:

The verification and validation tests performed demonstrated that the ECG data and ST segment measurements received and stored by the ST Review Station maintained their integrity as obtained from the ELI 100/STM. Therefore, supporting the determination of substantial equivalence while demonstrating its safety and effectiveness.

ST Review Station
510(k) Summary

Attachment 1

Tabular Comparison of Predicate Device's

Features	ELI 100/STM (K895232) Predicate Device	ST Central Station (K922927) Predicate Device	ST Review Station (K942685) Premarket Notification
Computer Based System	No -- 12-lead EKG that provides continuous and simultaneous monitoring of the ST segment	Yes -- Central display of ECG data in real-time for up to 8 patients acquired from the ELI 100/STM	Yes -- Allows for the review and storage of ST monitoring sessions from the ELI 100/STM
Color Monitor Display	No -- LCD display	Yes	Yes
Receives 12-lead EKG Data from Electrocardiograph	No -- 12-lead EKG with continuous ST segment monitoring	Yes	Yes
Displays ST Segment Changes	No -- Only prints 12-lead ST segment changes	Yes -- Optional 2-hour ST trend for the displayed ECG lead	Yes -- Displays entire ST trends and templates from ELI 100/STM monitoring session
Storage of 12-lead ST Segment Monitoring	Yes -- 900 to 1800 ECG's, Stores a single patient's continuous 12-lead ST segment monitoring session	No	Yes -- 25,000 to 37,000 Allows for the storage and review of multiple patient ST segment monitoring sessions
Displays 12-lead ECG	No -- Print only	Yes -- Continuous display of real-time ECG data on up to 8 patient's (Can display either median beat ECG, ST trends, or HR trends)	Yes -- Allows for the review of entire monitoring sessions stored median beat ECG, ST trends, and HR trends for a selected patient record
Automatic Template Update	Yes -- Compares successive 12-lead EKG to updated template for detection of significant ST segment changes	No	No
Display of Scanning and Serial Comparison	No -- Print of serial comparison	No	Yes -- Allows for the review of averaged stored ST complexes using superimposition scanning and serial comparison

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Features	ELI 100/STM (K895232) Predicate Device	ST Central Station (K922927) Predicate Device	ST Review Station (K942685) Premarket Notification
Display and Printing of Trends and Graphic Data	No -- Print of ST trends	Yes -- Can display the most recent 2-hours of either the HR or ST trends received from the ELI 100/STM and the most recent 2-hours of both HR and ST trends of the displayed ECG can be printed	Yes -- Can display and print a 3D color image of ST segment changes for all 12-leads along with HR and ST trends from a patient's entire ELI 100/STM monitoring session
User Defined Alarms	Yes -- One lead and two lead ST segment alarm thresholds	Yes -- High and Low HR alarms and ST segment alarm thresholds as established at the ELI 100/STM	No
12-Lead ECG Printouts	Yes -- 4 inch format	Yes -- 8.5 x 11 inch format	Yes -- 8.5 x 11 inch format
Patient Information	Name and ID #	Name and Room # -- (Name originates from the ELI 100/STM)	Name -- (Name originates from the ELI 100/STM)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Scott J. Pease
Mortara Instrument, Inc.
7865 North 86th Street
Milwaukee, Wisconsin 53224

AUG 12 1997

Re: K942685
ST Review Station
Regulatory Class: II (two)
Product Code: 74 DXJ
Dated: May 13, 1997
Received: May 16, 1997

Dear Mr. Pease:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health